Ex. C

(Excerpts from Hearing on Motion to Dismiss)

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC.,)
)
Plaintiff,) 2:06-cv-02768-MSG
)
vs.) Philadelphia, PA
) October 22, 2009
CEPHALON, INC., ET AL.,)
)
Defendants.)

TRANSCRIPT OF ORAL ARGUMENT ON MOTION TO DISMISS
BEFORE THE HONORABLE MITCHELL S. GOLDBERG
UNITED STATES DISTRICT JUDGE

APPEARANCES:

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ESR OPERATOR: STEPHEN SONNIE

Proceedings recorded by electronic sound recording.

MR. SODIKOFF: Yes, sir.

THE COURT: Okay. I'm listening.

MR. SODIKOFF: Apotex is a generic manufacturer of drugs and it has invested substantial assets to develop a generic version of modafinil. The investment that Apotex has made so far has included formulating a tablet, conducting extensive stability and bioequivalence testing, drafting and submitting proposals and ANDA to the FDA to obtain approval. And through Apotex's efforts, it has been able to obtain tentative approval from the FDA to market modafinil. So the -- Apotex has met all the scientific requirements to get its modafinil on the market. However, Apotex is not on the market and cannot get on the market because of the actions taken first by Cephalon and then joined by the generic defendants.

Before the break, this Court asked, "What does Apotex seek here?" Apotex has claims that I divide into two main categories. The first would be declaratory judgment patent claims, and the second would be our antitrust/ --

THE COURT: Well, I know what your claims are. My question was what's your advice to me as to how I proceed on those two separate companies?

MR. SODIKOFF: Your Honor, we've --

THE COURT: Aside from you want me to deny their motion to dismiss.

MR. SODIKOFF: Right. The 516 patent the defendants have admitted, we have jurisdiction over. The 346 patent I'll go into. I think it's pretty clear we have jurisdiction under Caraco. We would like to have those separated from the rest of the claims in this action and move forward expeditiously. We're, I think, scheduled to receive the documents from the defendants tomorrow pursuant to this court's order. We'd be ready for summary judgment in six months and a trial within a year.

We think that everything that you've heard here today really imbues Apotex's purpose here of entering the market with a generic modafinil product and we'd like the opportunity to get there. And if we're allowed to move forward with our declaratory judgment claims on the 516 and 346 we can finally break the bottleneck that the Cephalon and generic defendants have created.

I believe we've moved for bifurcation or I think under -- I can't recall the rule right now, another type of separation, I think that's pending before the Court; it might actually have been dismissed leading up to this, but we could re-brief the Court or rely on the pleadings thereof.

THE COURT: I think -- and I'm just guessing, but I think it was dismissed when I first got reassigned the case to without prejudice.

MR. SODIKOFF: Correct.

THE COURT: And if you want to -- have you re-filed that motion? I mean if you want to press that, if you want to press it here, re-file it.

MR. SODIKOFF: Okay. Thank you, Your Honor.

I'd like to turn --

THE COURT: Before you get to your argument on motion to dismiss, very briefly from Mr. Burling and Mr. Lefkowitz, what's your reaction to Apotex's request that we give them a separate scheduling order on the patent claims, six-month discovery period and trial in a year?

MR. BURLING: Well, Your Honor, I think for a number of reasons there's --

THE COURT: Assuming I deny your motion.

MR. BURLING: There's some great difficulty in having cases go forward separately and let me explain why.

THE COURT: Okay.

MR. BURLING: The overlaps are really -- again, depending on how you handle the motion to dismiss it makes severance difficult.

First of all, many of the plaintiff's antitrust theories and claims that you've heard, we'll, we don't think they're credible claims. If they were to go forward, Your Honor, were to describe, for example, that the underlying patent merits needed to be examined as part of the antitrust case, having them examined once in the context of the Apotex

516 claims and then a second time separately in the context of the antitrust case, particularly if discovery on one started before the other, you'd have completely duplicative discovery, redundant depositions, you know, there's every reason to put all of the merits of discovery on the 516 together if there is going to merits of discovery. Obviously, if Your Honor dismisses all the antitrust claims, that's a different situation. But you have --

THE COURT: But you and Mr. Lefkowitz, I think, have said, "Well, there really is no bottleneck. Apotex can just prosecute their patent claim." So are you suggesting that I prioritize my decisions of, well, there's going to be some duplication, Judge, so delay the prosecution of the patent claim because there's going to be duplication over there, right, which you recognize and really takes care of the bottleneck to prosecute their patent claim?

MR. BURLING: Well, I'm not arguing for delay for the sake of delay, if you would, Your Honor. This is going to be an enormous -- if it goes forward, an enormously burdensome and expensive case with lots of discovery.

THE COURT: But you guys keep saying it's -- you say "There's no bottleneck problem, Judge. Let them prosecute their case." But now you're saying it's going to be burdensome and expensive.

MR. BURLING: No. The --

THE COURT: Of course it's going to be burdensome and expensive.

MR. BURLING: I think they should prosecute their case. But what I was about to say is that separating it so that all the discovery has to be done once in the patent case and then potentially at a later time in the antitrust case adds -- increases that burden. Beyond that, and therefore we're not arguing for delay, we're arguing simply that when the case goes forward we do the 516 merits discovery if there is such a discovery that pertains to the antitrust case also at the same time. So the inventor deposition, we have all the parties who want to depose the inventor in the room who ask their questions at the same time. We don't have to call each witness back twice; once for a deposition in the antitrust case, a second time for a deposition in the patent case.

THE COURT: There's got to be a way to do it. I mean I realize this is an incredibly complicated case but there's got to be a way for what you and Mr. Lefkowitz say that is let them prosecute their case and get rid of the bottleneck. There's got to be a way to envision their day in court without getting caught up.

MR. SODIKOFF: Your Honor, I -- just to weigh in, Apotex does not expect to take significant discovery on the patent claims because we're getting all the discovery already. So, I mean, deps of inventors we maybe want a half day just if

we have any follow-up questions. I don't think there's going to be a lot of other depositions that we even want. So to take the step now to delay this --

THE COURT: Well, I'll look for your motion.

MR. SODIKOFF: Thank you, Your Honor.

THE COURT: And I kept interrupting Mr. Burling, I'll let you finish and then Mr. Lefkowitz can chime in if he wants.

MR. BURLING: Yes, the last thing I said, we will respond in detail in opposition to the motion. But another difficulty, I don't quite know how to come at this is the declaratory judgment counts on the 516 patent include, for example, a patent misuse count.

Now, separating a patent misuse count from a patent infringement count, I think, not only is inefficient, I'm not sure that really complies with the claim splitting principles or whatever.

The patent misuse count, as I explained, I think, yesterday morning, the definition of misuse is going beyond the bounds of the patent and excluding, that's exactly what we would be examining in any antitrust claim that went forward. The misuse claim in substance is really more of a competition claim, same as an antitrust claim even though in the end it pertains to the enforcement of the patent. So -- unless they waive their misuse plan, I don't know, but there is an overlap

there that's very difficult to escape in a motion.

THE COURT: Sure. I'm sure it is.

MR. SODIKOFF: I would like to --

THE COURT: Mr. Lefkowitz, you want to be heard?

MR. LEFKOWITZ: Yes, Your Honor, we certainly would be very comfortable having the patent case proceed as expeditiously if the Court is able to hear it. And we would, obviously, second I think everybody's view that we should try to avoid duplicative discovery.

THE COURT: Of course.

MR. LEFKOWITZ: But we're very comfortable there.

THE COURT: Okay. Great.

MR. LANGER: It's Howard Langer for Apotex. I think the one thing that --

THE COURT: How do you spell your last name, please?

MR. LANGER: L-A-N-G-E-R.

THE COURT: Go ahead.

MR. LANGER: I think that what's clear from Your Honor's question and what's clear from everything you've heard the last two days is that if the patent case were put on anything near the track of the antitrust case we would be spinning wheels in the patent case. It would be of very limited value to Apotex which filed it several years ago and has been trying to come to market for several years. So that the need to sever it and move it quickly is really a function

of whether the case is going to provide any use plus --

THE COURT: Well, I'm -- I think I'm going to be very receptive to that and very receptive to the argument in light of Cephalon and the generics continued argument that the bottleneck is not an issue here. You can prosecute your patent case. Well, let's take them up on it and let's get the patent case moving. I'm not making that decision now. I'm saying we have to consider their response and I realize now I'm backing myself into a corner. Giving myself more work immediately but I just think the defense and if we insist on their position and I think they -- I'm not saying they're being inconsistent, particularly Mr. Lefkowitz's response, but I'll take a look at what you want to file. Okay. So go ahead.

MR. SODIKOFF: Thank you, Your Honor.

I'd first like to go into our antitrust claims and then kind of sweep up the declaratory judgment claims at the end. I won't speak to the tortious interference claims because I think we're comfortable with resting on our briefs on that as well.

THE COURT: Very well.

MR. SODIKOFF: And when I'm complete, Mr. Langer has a short section also.

THE COURT: Okay.

MR. SODIKOFF: Throughout the last two days, the

defendants have told this Court that there is no circuit split, but they haven't really gone through what the implications of that argument are and what that necessarily means. And what it means is that each of the cases that have been decided before this one, Tamoxifen, Cipro, Cardizem, Valley Drug and the rest, were decided on their particular facts. And that the particular facts in each of those cases what was ultimately determinative and that is very critical for where we are right now in a 12(b)(6) in that we haven't developed all the facts. So if there is one case law and different circuits are coming out with different decisions, necessarily it's the facts that are different and we need to develop the facts here to see which one we're closest to.

I think it also means necessarily that the scope of the patent is not outcome determinative. It is but one factor to weigh in the balance between the actual adverse affect on competition and the pro-competitive redeeming virtues of the agreements.

THE COURT: Could you go back, you said the scope of the patent is what?

MR. SODIKOFF: It cannot be outcome determinative. That is, it's not just scope of the patent, I apply that legal rule and I throw the case out.

THE COURT: Well, why can't I -- why can't I just look at the scope, examine the patent -- look at the scope of

the patent and examine the agreements with the generics? Why can't I do that?

MR. SODIKOFF: I'll go into it in a second and show later that there's a lot of factual issues that are involved there.

THE COURT: Okay.

MR. SODIKOFF: Secondly, that would not be consistent with In re Cardizem because while In re Cardizem was an interim agreement, there is no question that it was within the scope of the patent. A great part of it was keeping a generic off the market which is within the scope of the patent and still the Sixth Circuit held that it was an illegal arrangement and in fact, per se, illegal. So you can have something occur within the scope of the patent and I'd also like to cite the U.S. v. Singer case. There, the plaintiff, and this is a Supreme Court case that's briefed in our opposition, the plaintiff had a valid issued patent and decided to pursue it against only Japanese manufacturers. There was no claim that the actual infringement suit was a fraud or a sham. Yet, the Supreme Court still held that pursuing these Japanese competitors was illegal under the antitrust laws. That is, the actual litigation was within the scope of the patent yet it was still an antitrust violation and the Supreme Court looked at the intent and scope and the purpose of the parties in what they did. And there they

colluded in an interference proceeding to get a patent but there's no allegation that the patent wouldn't have issued anyway. And here you have the generic defendants in Cephalon colluding to abuse the Hatch-Waxman Act to create these bottlenecks and also to enforce them against certain competitors like Apotex. The net result here is that Cephalon and the generic defendants are sharing monopoly prices and have come together to enforce the patent against all other comers. And I'll get into a little more about the bottleneck later.

So the key thing in Cardizem was that there was no final settlement and that when the Court looked at that and they were weighing the pro-competitive versus the anticompetitive, they took off that pro-competitive justification and the balances swayed. And that's what you have to do in every court, Your Honor -- in every case.

THE COURT: This is a Sixth Circuit case?

MR. SODIKOFF: That's a Sixth Circuit case.

And what we suggest is that even the Second Circuit and the Fed Circuit, which is applying Second Circuit law in Cipro, applies the rule of reason test.

And I'd like to read just one quick statement. This is from the In re Cipro case reviewing a district court opinion. And it says at 544 F.3d 1332, "Under the law of the Second Circuit, the rule of reason analysis is a three-step

process. First, the plaintiff bears the initial burden of showing that the challenged action has had an actual adverse effect on competition as a whole in the relevant market. Then, if the plaintiff succeeds, the burden shifts to the defendant to establish the pro-competitive redeeming virtues of the action." And then finally, "Should the defendant carry this burden" and this is one of Apotex's arguments, "the plaintiff must then show that the same pro-competitive effect could be achieved through an alternative means that is less restrictive on competition." And I think we'll get to this in the bottleneck that the Cephalon and the generic defendants certainly could have settled in a way that was an alternative means that would be less restrictive of competition.

So even under the Second Circuit in the Cipro case, Tamoxifen and Cipro, the court -- the district court went through the specific facts alleged there and found, ultimately, that there was no antitrust violation. But what I'd like to do is show how the facts that are alleged by Apotex are outside of what was considered by Cipro and Tamoxifen, and in fact, Apotex alleges things that in dicta the Cipro court and the Tamoxifen court, the two cases primarily relied on by the defendants, actually said that would be an antitrust violation.

So ultimately what Apotex is looking for is quite simply an order that says the motion for -- is denied. And

it's denied because there are many questions of fact that need to be resolved in order to weigh in the rule of reason analysis whether there are pro-competitive benefits that outweigh and are the least restrictive necessary.

THE COURT: Isn't that a pro-competitive benefits that are what? Say it again.

MR. SODIKOFF: The rule of reason weighing analysis looking at whether the pro-competitive benefits such as the final settlement is --

THE COURT: Right. The facts that are -- that I have to look at to come to that determination are what? The settlement agreements and the patent, right?

MR. SODIKOFF: No, and additional things which I'd like to go into.

THE COURT: Go ahead.

MR. SODIKOFF: There's three main things here that Apotex alleges that show that the patent is -- that what Cephalon has done here is outside the scope of the patent. The first one is fraudulent procurement and sham litigation. The second is that it covers noninfringing substitutes.

THE COURT: Hold on for a second.

MR. SODIKOFF: Sure.

THE COURT: Because saying fraud and sham those aren't facts; those are allegations.

MR. SODIKOFF: Right.

THE COURT: What are the facts?

MR. SODIKOFF: The facts are, and I'm going to grab my --

THE COURT: Yes, go ahead. Sure.

MR. SODIKOFF: And this is just one of Apotex's allegations in its complaint and this is paragraph 29. And it begins with -- and it's long and it has a lot of specific facts but --

THE COURT: You don't have to read it, you can summarize it. I'll read it.

MR. SODIKOFF: I won't read it. I'll summarize it.

Basically, Apotex looked at what the generic defendants alleged in their inequitable conduct case. The specific facts that were alleged there that were not this move to dismiss by Cephalon that showed inequitable conduct if assumed as being true. And Apotex put each of those specific facts in its allegations here. And next week we can probably supplement instead of on the information in belief if necessary we could put in -- we now have actual knowledge because we'll have those documents that the defendants relied on.

THE COURT: Knowledge of what?

MR. SODIKOFF: I'm sorry.

THE COURT: Knowledge of what?

MR. SODIKOFF: We'll have actual knowledge of our

facts here. Right now, we've alleged them.

THE COURT: Summarize the facts for me. What are the facts?

MR. SODIKOFF: Sure. The facts are that during the prosecution of the patent, the attorneys for Cephalon and others who are involved with the prosecution of the patent committed inequitable conduct and committed fraud on the patent office by doing numerous acts that are alleged in 23 through 39 of our complaint, they include the fact that they deliberately did not tell the patent office that it was Lafon (ph.), a French company, that was, in fact, the inventor of modafinil as well as the particle size limitations.

THE COURT: How are you going to prove that?

MR. SODIKOFF: How am I going to prove that?

THE COURT: Yes, sir.

MR. SODIKOFF: Eventually, we'll prove that with the documents from Cephalon; their correspondence with Lafon showing that Lafon actually told this stuff to Cephalon and these are the precise allegations made by the generic defendants when they saw those exact documents.

We're also going to prove and -- Your Honor, at this stage, these facts should be assumed as true. They're specific.

THE COURT: Right. I'm not challenging you on are your facts right, I just want to know what they are.

MR. SODIKOFF: Okay.

THE COURT: You say fraud and sham and collusion, those are conclusory statements.

MR. SODIKOFF: Sure. Let me step back a little bit --

THE COURT: I want you to stay on the same track. You're going to present facts to show that it was a fraud and a sham because you're going to be able to present evidence that there was some type of misrepresentation regarding the actual inventor, correct?

MR. SODIKOFF: Right.

THE COURT: What else?

MR. SODIKOFF: What else? They also had an on-sale bar.

THE COURT: A what?

MR. SODIKOFF: An on-sale bar.

THE COURT: What's that mean?

MR. SODIKOFF: An on-sale bar is 35 U.S.C. Section 102(b). It is clear and objective standard that if something was on-sale in the United States more than one year prior to the application, it bars getting a patent on what was on-sale. And we have alleged and we'll prove that Cephalon -- that the modafinil product that is claimed here was subject to the on-sale bar because it was, in fact, purchased from Lafon prior to the one year filing date under 35 U.S.C. 102.

THE COURT: And Lafon is the French manufacturer you referenced?

MR. SODIKOFF: Correct.

THE COURT: Okay. And as to the other facts regarding fraud and sham you said paragraphs 29 through 32 of your complaint?

MR. SODIKOFF: Twenty-three through thirty-seven, Your Honor. I'm sorry. I think I said 23 to 39 but it's 23 to 37.

THE COURT: That's fine. Okay.

MR. SODIKOFF: They name specific people, facts, dates, specific statements made by each person. I can get the complaint and go through each.

THE COURT: You don't have to do that because we're going to read them

MR. SODIKOFF: Right. And the facts that we allege in our complaint which must be assumed is true, are more than what the federal circuit has found to be sufficient to allege fraud and to actually prove fraud in the case. And the looming case there is Noblepharma. It's a Fed Circuit, I believe -- I can't recall the year; maybe 2003. It's in our brief.

THE COURT: It's in your brief, right?

MR. SODIKOFF: It's --

THE COURT: Don't worry about the cite.

MR. SODIKOFF: Sure.

THE COURT: If it's in your brief it's fine.

MR. SODIKOFF: It's in our brief. And the Noblepharma case, what happened there was the inventor gave something to his patent attorney and it ended up not making it before the PTO.

And when you go to get a patent, it's an ex parte procedure when a patentee or an applicant does. And the patent office has a duty of candor because the patent office is not experts like the applicant is. They have one -- usually one examiner. He can usually spend one day to examine an application at most. He's busy and he just doesn't have the time. And so there is a burden and a duty that's not disputed by the defendants of candor where you have to be good faith, you cannot lie, you cannot make material omissions.

And in the Noblepharma case, the piece of prior art was given to the prosecuting attorney, it didn't make it to the patent office. The prosecuting attorney said "I never have bad intent, generally. I would have definitely given it over if I thought it was important. But I don't remember specifically what happened." And the Fed Circuit affirmed the jury finding of an antitrust violation for fraud on the patent office.

The jury was allowed to infer that this man convicted inequitable conduct. That he withheld this on purpose even

though there was no direct testimony of it. And there's legion federal circuit cases that say that circumstantial evidence is sufficient because that's usually all that exists. It's very rare to have a patent attorney say I purposely lied to the patent office.

Apotex's complaint has these specific facts. They more than meet the Noblepharma standard. And they establish fraud on the patent office. So what does that mean? That means that the patent has no scope. There is no immunity. There is no scope of the patent test. Everything that they had done to decrease competition is an illegal restraint of trade under Walker Process, under Noblepharma.

They have two -- I'd like to call them arguments; they're not factual at all and they mention them on the opening. As arguments, they're no way pled by Apotex. They're not in our complaint. But what they've argued is that the generic defendants originally didn't file fraud so there must not have been. And that the FTC did not file an allegation of fraudulent procurement.

First, the generic defendants did allege inequitable conduct and the defendants have argued to this Court that there's a huge difference, or at least intimated it, but there's a big difference between inequitable conduct and fraud on the patent office. But if you review the case law, that's simply not the case. Inequitable conduct requires intent to

mislead the PTO. It requires a bad intent under Federal Circuit precedent and it requires materiality of what you withhold -- or what you misrepresent to the PTO.

The difference with fraud is that instead of having materiality, you have to have but for causation. The intent requirement is largely similar in most inequitable conduct cases. So the generic defendants allege that Cephalon had the bad intent required. And we adopt those exact same specific facts and we will plead that -- we plead them now and I think we have a reasonable basis for pleading them. They're plausible because they're taken directly from sworn pleadings from the defendants in this case.

And so the difference is that inequitable conduct is materiality. Fraud is but for causation. That but for their lie -- their omission, lie or omission, the patent would not have issued.

We've argued a 102(b) that they withheld a 102(b) invalidating reference that Cephalon and those who prosecuted the patent purposely withheld prior art that would invalidate the patent. That is but for causation. We allege a Walker Process violation. And if nothing else, Your Honor, you can dismiss their motions to dismiss because that exists and they've told us the last two days that we're -- a Walker Process violation exists. There clearly is an antitrust violation.